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10/821,939	04/12/2004	Tae H. Ji	028750-229	2139

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EXAMINER	
BORGEEST, CHRISTINA M	
ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
10/04/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/821,939	JI ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16 and 54-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16 and 54-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Rejections Withdrawn

Claim Rejections - 35 USC § 102

The rejection of claims 16, 54-56 under 35 U.S.C. 102(b) as being anticipated by Hsueh et al. (U.S. Patent 5,925,549, published 20 July 1999) as set forth at pages 11-12 of the Office action mailed 22 March 2007 is withdrawn. Upon further consideration, the teachings of the '549 patent are broader in scope then the claims and do not anticipate or render obvious the claimed methods.

Maintained/New Rejections

Claim Rejections - 35 USC § 112, first paragraph – Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicants' amendment of claim 16 has necessitated a new rejection under 35 U.S.C. 112, first paragraph.

Claims 16, 54-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." (See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 Fed. Cir. 1988) These factors include, but are not limited to: (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicants claim a method of preventing conception. To successfully prevent an outcome, a method must stop an outcome from occurring 100% of the time. No method of contraception (outside of hysterectomy) prevents pregnancy in every case (See Trussell J. Contraceptive failure in the United States. Contraception. 2004 Aug;70(2):89-96—cited in the Office action mailed 27 October 2005). It was known in the art at the time of application there was still no known 100% effective contraception outside of surgical sterilization. Regarding predictability within the art of contraceptive drug development, see In re Marzocchi:

> [I]n the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof.

A 100% effective method of contraception comprising administration of LHR^{exo2} or LHR^{exo3} was not known in the art at or around the time the application was filed. (See Trussell J. Contraceptive failure in the United States. Contraception. 2004 Aug;70(2):89-96). The specification gives no direction or guidance as to the identity of a 100% effective contraceptive method comprising administration of agents, nor are there any working examples.

Furthermore, to the extent that the specification intends to reduce the incidence of conception, the scope of the claimed methods is not commensurate with what is taught in the specification and the prior art. With the exception of the issue raised regarding LHR^{exo1}, which has been resolved due to Applicants' amendment to delete reference to LHR^{exo1} in the claims, the issues raised in the scope of enablement rejection as set forth at pages 3-8 of the Office action mailed 22 March 2007 are still of concern and that rejection is hereby applied to the instant claims.

Due to the large quantity of experimentation necessary to generate the muteins encompassed by the and screen same for the ability to prevent conception in a female, furthermore, the extreme unlikelihood that LHR^{exo2} and LHR^{exo3} polypeptides would **prevent** conception, the lack of direction/guidance presented in the specification and the absence of working examples directed to the same, the complex nature of the invention, the contradictory state of the prior art, the unpredictability of the effects of mutation on protein structure and function (see discussion at pages 3-8 of the Office action mailed 22 March 2007 and recited references), and the breadth of the claims

which fail to recite limitations on agents that block CG activity, undue experimentation would be required of the skilled artisan to make the claimed invention in its full scope.

Applicants' argue at p. 4, 2nd paragraph that the sequence of LHR^{exo2} and LHR^{exo3} were well known in the art at the time the invention was filed (and refer to Exhibit A attached to their response filed 6 November 2006 to provide evidence thereof). Applicants further argues at p. 4, last paragraph to p. 5, 2nd paragraph that LHR^{exo2} and LHR^{exo3} have the 80%, 90% and 91% sequence identity to the LHR^{exo2} and LHR^{exo3} of different animals. Applicants argue further at p. 5, last paragraph that since LHR^{exo2} is 20 amino acid residues in length and LHR^{exo3} is 11 amino acids in length, the limitations of "19-21 residues" for LHR^{exo2} or "10-12 residues" LHR^{exo3} that the amount of experimentation required to make peptides with an additional one or two residues would not be undue, and that the novelty of the claimed method lies not in the use of novel peptide sequences, but instead relies on the novel observation that exoloop domains of the LHR interact with chorionic gonadotropin (CG).

These arguments have been fully considered but are not found persuasive for the following reasons. Applicants are claiming a method of contraception, which amounts to a method of treatment and not merely a method of screening potential contraceptives; the art is complex and unpredictable. The skilled artisan would be required to identify a suitable variant of LHR^{exo2} having only 85% identity and 91% identity to the LHR^{exo3} to the human sequence, respectively, so it is not merely a matter of identifying peptides that work with an additional one or two residues. While the Examiner appreciates the inventive concept (i.e., the binding of LHR^{exo2} and LHR^{exo3} to CG), the standard for enablement in the instant case is that the claimed methods prevent conception, and not merely to screen for variants of LHR^{exo2} and LHR^{exo3} that may or may not bind to the CG.

Claim Rejections - 35 USC § 112, first paragraph – Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 16 and 54-56 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as set forth at pages 8-10 of the Office action mailed 22 March 2007 is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicants argue at p. 6, 2nd-3rd paragraphs that the novelty of the claimed method lies not in the use of novel peptide sequences, but instead relies on the novel observation that exoloop domains of the LHR interact with chorionic gonadotropin (CG), and that according to the holding in Falkner v. Inglis, there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of a known structure.

This argument has been fully considered, but is not found persuasive for the following reasons. First, the fact pattern in Falkner v. Inglis is not the same as the instant case. The Inglis patent, 5,770,212, is drawn to a vaccine and a method of producing a vaccine, whereas the instant methods are drawn to preventing conception (i.e., treatment). Although it is understood that the inventive concept is the ability of LHR^{exo2} and LHR^{exo3} to bind to CG, the instant claims are drawn to a method of preventing conception (treatment), and the specification does not provide evidence of possession

of the claimed genus of variants of LHR^{exo2} and LHR^{exo3} having 85% and 91% sequence identity, respectively, that are capable of preventing conception in a female.

Claim Rejections - 35 USC § 112, first paragraph – New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 16 and 54-56 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as set forth at p. 10 of the previous Office action mailed 22 March 2007 is maintained.

Applicants argue at p. 7, 2nd – 3rd paragraphs that it is clear that the sequence and structure of the LHR polypeptide was known to the skilled artisan at the time of the invention and cite Capon v. Eshhar.

Applicants' argument has been fully considered but is not found persuasive. Applicants do not specifically contemplate the recited fragments in the specification as originally filed, nor do those fragments flow naturally from the disclosure. Finally, Applicants cannot rely on prior art for written description in a new matter situation unless they have incorporated a specific prior art by reference in the original disclosure.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 7:00am - 1:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest, Ph.D.

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646